

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE, TENNESSEE

AMANDA PADGET,)
Plaintiff,) Case No. 3:13-CV-00998
vs.-)
COOK MEDICAL INCORPORATED) JUDGE HAYNES
a/k/a COOK MEDICAL, INC., COOK)
INCORPORATED, COOK GROUP, INC.,)
and WILLIAM COOK EUROPE APS,)
Defendants.)

~~JOINT PROPOSED INITIAL CASE MANAGEMENT ORDER~~

Pursuant to Fed. R. Civ. P. 26(f) and in accordance with Local Rule 16.01(d)(2), the parties respectfully submit the following proposed Initial Case Management Order for the Court's consideration.

I. JURISDICTION and VENUE: The Court has jurisdiction of this case pursuant to 28 U.S.C. § 1332(a)(1) and 28 U.S.C. § 1332(a)(2), and neither jurisdiction nor venue is disputed.

II. BRIEF THEORIES OF THE PARTIES:

a. PLAINTIFF:

With the exception of William Cook Europe APS based in Bjaeverskov, Denmark, all defendants are Indiana Corporations and regularly conduct business in Bloomington, Indiana. The injuries to the Plaintiff were preventable. Defendants knew or should have known that its device could penetrate the vena cava in the way it did and fracture. It knew, or at least should have known, that the Celect design was more prone to perforating the vena cava, fracturing and

migrating than other IVC filter designs. It also knew that the Celect design of these filters were not meant to remain in the human body for long periods of time and to do so would render the device unsafe. Yet, the Defendants failed to disclose these risks to the medical community, let alone the patients.

Plaintiff, Amanda Padget, had recurrent DVT's in her leg. Thus it was determined that an IVC Filter would be implanted. On November 2, 2010, the Cook Celect Filter was inserted into Plaintiff. There were no complications at that time. On September 25, 2012, Amanda Padget presented to the hospital to have the Cook Celect Filter removed. Unfortunately, it was unable to be removed. Upon closer examination, it was discovered that several struts of the filter had perforated Plaintiff's vena cava. The Cook Celect Filter currently remains inside of Ms. Padget. Ms. Padget is at risk for future Cook Celect Filter fractures and migrations. She faces numerous health risks, including the risk of death. For the rest of Ms. Padget's life, she will require ongoing medical monitoring.

b. DEFENDANTS:

This is a complex product liability action involving a Cook Celect® Vena Cava Filter ("Celect"), the intended use of which is for the prevention of recurrent pulmonary embolism via placement in the vena cava according to the Instructions For Use ("IFU") which accompany the device. The Celect filter was first approved for sale in the U.S. in 2007, but the predicate device, the Günther Tulip® Vena Cava Filter, was first released for sale in 1992 and has been on the U.S. market since 2000. These devices, however, have a longer history and have been available for sale outside of the U.S. since 2006 and 1992. Both devices are manufactured by William Cook Europe ApS ("WCE"), which is located in Bjaeverskov, Denmark.

Defendants have been informed through Ms. Padget's Complaint that the following events allegedly have occurred: Due to deep vein thrombosis in her legs, a Celect was implanted in her inferior vena cava ("IVC") on November 2, 2010, without complications; on or about September 25, 2012, the IVC filter was unable to be removed because "several struts of the filter had perforated" Ms. Padget's vena cava; and now Ms. Padget alleges she is at risk of fractures and migrations of the IVC filter, that she faces numerous health risks, including death, and will require on-going medical monitoring for the rest of her life.

Based on what has been reported to Defendants as described herein and Defendants' investigation and analyses to date, including analysis of the applicable design, manufacturing and quality control records, Defendants deny that the IVC filter implanted in Ms. Padget was defective in any way, that it was negligent in any way, that it breached any type of express or implied warranty and that Ms. Padget is entitled to punitive damages. Defendants will need a signed medical authorization for the release of Ms. Padget's hospital and medical records, including imaging, to fully evaluate Ms. Padget's claims.

Even if the IVC filter did perforate the caval wall, perforation is a rare potential adverse event. Cook's IFU, which accompany the device, warn of potential adverse events, including damage to the vena cava and vena cava perforation. In addition, the device may be retrieved under the circumstance described in the IFU, and in accordance with the "Optional Retrieval Procedure" described in the IFU. Furthermore, the Celect was designed and was first approved by the United States Food & Drug administration ("FDA") for *permanent placement*, and only subsequently approved for retrieval. Cook has no duty to warn the plaintiff of such adverse events, as its duty is to warn the learned intermediary, the physician who implanted the device, a duty which it discharged through its IFU approved by the FDA.

III. SCHEDULE OF PRETRIAL PROCEEDINGS

a. Rule 26(a)(1) INITIAL DISCLOSURES

The parties will exchange their Initial Disclosures within (30) days from the date of the initial case management conference. Plaintiff is to include copies of any hospital and medical records, including imaging, and any Lot # information as part of her disclosures.

b. Meeting of Counsel and Parties to Discuss Settlement Prospects

March 7, 2014
On or before ~~February 20~~, 2014, counsel and clients are required to have a face-to-face meeting to discuss whether this case can be resolved without further discovery proceedings. If a party, other than a natural person, is involved in this litigation, a representative who has authority to settle shall attend this meeting on behalf of that party. After the meeting is conducted, counsel shall prepare a report and file it with the Court reflecting that the parties met and that the parties made a good faith effort to evaluate the resolution of this case. This report should also include whether the parties believe that one of the Alternative Dispute Resolution ("ADR") procedures under Local Rules would further assist the parties in resolving this matter.

c. Other Pretrial Discovery Matters

As determined at the case management conference on Friday, November 22, 2013, this action is set for a jury trial on *September 15, 2015* at 9:00 a.m.

If this action is to be settled, the Law Clerk shall be notified by Noon, *September 11, 2015*, *Monday, August 31, 2015*. If the settlement is reached thereafter resulting in the non-utilization of jurors, the costs of summoning jurors may be taxed to the parties dependent on the circumstances.

A pretrial conference shall be held on August 31, 2015 at 3:00 pm *[Signature]*
m. A proposed pretrial order shall be submitted at the pretrial conference.

All discovery shall be completed by March 3, 2015. All written discovery shall be submitted in sufficient time so that the response shall be in hand by March 3, 2015. All discovery related statements shall be submitted in sufficient time so that the response shall be in hand by March 10, 2015. No motions related to discovery or for a protective order shall be filed until a discovery/protective order dispute conference has taken place and the attorneys of records shall attend and meet, face-to-face, in an effort to resolve the dispute and a jointly signed discovery/protective order dispute statement is submitted setting forth precisely the remaining issues in dispute and the reasons why those issues remain unresolved.

All dispositive motions and *Daubert* motions shall be filed by May 1, 2015, and any responses thereto shall be filed by June 1, 2015. Any replies shall be filed by June 16, 2015.¹

Any motion to amend the pleadings or join parties shall be filed in sufficient time to permit any discovery necessary because of the proposed amendment to be obtained within the time for discovery. No amendment will be allowed if to do so will result in a delay in the disposition of the action by requiring an extension of the discovery deadline.

There will be no stay of discovery pending disposition of any motions.

Interrogatories pursuant to Rule 33, Federal Rules of Civil Procedure, shall be limited to sixty (60) such interrogatories. Subparts of a question shall be counted as additional questions for purposes of the overall number.

In all other respects, Rule 33.01, Local Rules of the Court shall govern.

By November 4, 2014, the plaintiff shall declare to defendants (not to file with the Court) the identify of her expert witnesses and provide all the information specified in Rule 26(a)(2)(B).

¹ Strict compliance is required to Rule 56.01, Local Rules of Court, relating to motions for summary judgment.

By December 4, 2014, the defendants shall declare to the plaintiff (not to file with the Court) the identity of their expert witnesses and provide all the information specified in Rule 26(a)(2)(B).

Any supplements to expert reports shall be filed by January 13, 2015. There shall not be any rebuttal expert witnesses.

To reduce the needless expenditure of time and expense, there shall not be any discovery depositions taken of expert witnesses. A party may, however, serve contention interrogatories and requests for admission and production upon another party's expert. If these discovery methods prove ineffective, a party may move to take the deposition of the expert. In a diversity action, a treating physician is considered a fact witness unless the physician expresses opinions beyond the physician's actual treat of the party.

The expert witness report required by Rule 26(a)(2)(B), Federal Rules of Civil Procedure, is considered to be the direct examination testimony at trial. If an expert expects to expound his or her testimony beyond the wording of the expert's report, the party calling the expert shall inform the opposing party with the specific of that expounding testimony at least 15 days prior to the dispositive motion deadline.

These rules on experts are to ensure full compliance with Rule 26(a)(2); to enable the parties to evaluate any *Daubert* challenges prior to filing dispositive motions; to avoid conflicts with experts' schedules; and to avoid the costs of expert depositions.

Local Rule 39 (c)(6)(c) relating to expert witnesses shall apply in this action, and strict compliance is required.

IV. OTHER DISCOVERY MATTERS:

a. Medical Authorizations

Plaintiff shall provide signed medical authorizations or objections thereto to Cook by December 6, 2013. Copies of all hospital and medical records obtained by Cook will be provided to plaintiff.

b. Electronic Discovery

Based on the allegations in Padget's complaint, the parties discussions both in this case and the other pending related actions, and the requests for production of documents provided in another related action, the parties anticipate a substantial volume of documents will be produced in this matter. Cook Defendants have entered into an agreement with an E-discovery or electronically stored information ("ESI") vendor and will be working with Plaintiff's counsel to develop an ESI protocol. In order to develop an ESI protocol and identify the sources of ESI in this matter lead counsel for Cook Defendants, Douglas King, spent three days at WCE.

Cook Defendants anticipate initial ESI discussions with Plaintiff's counsel in this matter and with counsel involved in the pending related actions will take place in the next two weeks. The discussions will include those topics covered in the Court's Administrative Order No. 174.

In the meantime, Cook Defendants have prepared an Initial Production of Inferior Vena Cava Filter documents, totaling over 10,000 pages. Cook Defendants have agreed to make these documents available to Plaintiff's counsel in this matter, and in the related actions pending in other jurisdictions, subject to entering into an Agreed Protective Order ("Agreed Orders"). The Parties anticipate filing an Agreed Protective Order in this matter.

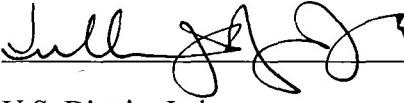
c. Related Matters

There are sixteen related matters pending in other jurisdictions. The related actions are as follows:

	Style	Jurisdiction	Action Number
1	Adams et al. v. Cook et al.	USDC, S. Dist. of IN	1:13-cv-0013
2	Brady et al. v. Cook et al.	USDC, Central Dist. of CA	2:13-cv-4725
3	Brand et al. v. Cook et al.	USDC, N. Dist. of GA	1:13-cv-1469
4	Cadle v. Cook et al.	USDC, N. Dist. of OH	5:13-cv-01255
5	Huffman et al. v. Cook et al.	USDC, Dist. of NV	2:12-cv-2000
6	Jung v. Cook et al.	USDC, S. Dist. of IN	1:13-cv-0925
7	Metro v. Cook et al.	USDC, S. Dist. of IN	1:13-cv-1048
8	Naly v. Cook et al.	USDC, S. Dist. of IN	1:13-cv-0986
9	Perry-O'Farro et al. v. Cook et al.	USDC, E. Dist. of NC	5:13-cv-587
10	True v. Cook et al.	USDC, Dist. of NV	2:13-cv-0413
11	Walck v. Cook et al.	USDC, M. Dist. of PA	3:13-cv-1839
12	West et al. v. Cook et al.	USDC, N. Dist. of WV	5:13-cv-109
13	Wonder v. Cook et al.	USDC, M. Dist. of PA	1:13-cv-2288
14	Crull v. Cook et al.	Marion (County, IN) Sup. Ct.	49D10-1208-CT-034324
15	Messer et al. v. Cook et al.	Marion (County, IN) Sup. Ct.	49D07-1310-CT-36987
16	Williams v. Cook et al.	St. Joseph (County, IN) Sup. Ct.	71D04-1302-PI-043

The parties have discussed, and have been working on, coordinating the schedules for discovery and possibly also coordinating any discovery disputes that may arise in any of the related cases. Wherever possible and feasible, the parties have used the same deadlines or, at a minimum, the same overall timeline for the case, in this proposed Initial Case Management Order as those entered by U.S. District Judges in other Jurisdictions.

IT IS SO ORDERED.



U.S. District Judge

Date: 11-26-13